

**International Conference on Harmonization (ICH)**  
**M2 EWG Meeting - Summary**  
**Tokyo, 21 May - 24 May 2001**

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**Participants:**

**EU:** Stan van Belkum, Miguel Bley, M. T. Carrasco Benitez, Tim Buxton  
**EFPIA:** Gabriele Disselhoff, Andrew Marr, Raj Long  
**FDA:** Greg Brolund (Rapporteur), Melissa Chapman, Bill Ridgely, Norman Schmuff  
**PhRMA:** Kris Arora, Bob Hizer  
**MHLW:** Mihoko Okada, Mitsuo Saito, Hiroshi Yamamoto, Tetsunari Kihira  
**JPMA:** Yuichi Nagoshi, Tetsuro Shimokariya, Hitoshi Asano, Harv Martens, Keiji Sawamukai, Masatochi Ozeki, Tadao Akiyama, Koichi Takahashi  
**Observer:** Louis Boulay, Tomas Hansson, (Canada), John Hems (IGPA), Andreas Franken (WSMI)

Following actions have been taken / agreements were reached:

- The comments of FDA, PhRMA and EU on the draft of the specification document were discussed and appropriately actioned. It was agreed that a major reorganisation of the specification document is necessary, but that it will be undertaken in the final step 2 document.
- The comments from FDA, EU, PhRMA and JPMA on the draft DTD were discussed and appropriately actioned.
- DTD 0.9 dated May 24, 2001, was agreed and will be frozen (for anything else than direct bug fixes) until the October 2001 meeting.
- FDA demonstrated their version of the eCTD transformation tool based on DTD version 2.51.
- Outstanding questions on numbering and repeating elements with the IWGs Q, S; E were clarified and resolved.
- The Step 2 eCTD for Testing Table of Contents was signed by the six parties. That represents commitment to the content and principles in the current draft specification and DTD.
- FDA will edit all documents which are part of the Step 2 eCTD for Testing Table of Contents for consistency and format and will distribute it by June 24, 2001. Comments and changes may be submitted through September 15, 2001. A final version for discussion will be distributed by October 1, 2001.
- A test protocol was developed and version 0.1 has been agreed in principle. Regions have agreed to progress formal testing in time to report back for the October 2001 EWG.

**Documents distributed:**

- 1 page summary
- All documents of Step 2 eCTD for Testing Table of Contents

The next meeting is in Brussels, October 22 - 25, 2001.